

controlled conditions in sufficient quantity to conduct the side-by-side testing of products. Applicants are encouraged to discuss with CBER what data are necessary to compare products, as such data may range from analytical testing to full clinical trial(s).

7. Review timeframes and submission times

There may be cases where applicants wish to submit an ELA for a pilot facility prior to submitting a companion PLA. A statement that the facility is ready for inspection at the time of submission should be included. FDA ordinarily intends to inspect at the time the facility is manufacturing the product for which licensure is sought. It is possible that, in some cases, inspection of the establishment could take place before the submission of the PLA. It is also possible for the ELA to be submitted after the PLA as discussed above.

CBER intends to review PLA's and ELA's submitted at different times under the normal timeframe targets of the managed review process (from the date of receipt at CBER, 12 months for standard and 6 months for priority applications; 6 months for supplements). CBER intends to issue the appropriate action letter (approved, approvable, or not approvable) to complete its action on any application.

Applicants should be aware that submitting the ELA and PLA at separate times will not necessarily reduce the approval time when compared to concurrent submission. Early submission of applications may, however, allow earlier feedback from CBER on deficiencies in an application that can be addressed by the applicant sooner than would otherwise be possible. In all cases described above, CBER intends to approve PLA's, ELA's, or supplements concurrently.

In cases of shared manufacturing arrangements (see 57 FR 55544 at 55545), the PLA's for the intermediate product(s) and end product should be submitted concurrently in order for a complete review of the product to occur, since determining the approvability of the end product will depend upon information in the intermediate product PLA's. The ELA's may be submitted at different times from the PLA's.

Applicants should consider carefully the consequences of the timing of any submission on the use of CBER resources. It is expected that applicants will use the flexible submission times in cases of need. Applicants should recognize that the filing of submissions which are premature or incomplete will result in unnecessary resource commitments by CBER and the applicant. It is therefore recommended that applicants do not submit an ELA before favorable preliminary data or information from clinical trials of the product is available. For products intended for use in serious and life-threatening diseases, applicants should consider submitting the ELA and PLA concurrently to prevent a situation from occurring where otherwise approvable product cannot be approved because the facility is not yet ready to be licensed.

If a scenario exists that is not covered in this guidance document, the applicant should seek guidance by contacting the appropriate applications division in the

Offices of Therapeutics Research and Review, Blood Research and Review, or Vaccines Research and Review, or the Division of Establishment Licensing.

8. Availability of product at the time of licensure

If an applicant requests licensure for a pilot facility, this choice may affect the amount of product available at the time of approval. For important new products for use in treating serious and life-threatening illnesses, the ramifications of limited availability of the product at the time of approval should be assessed by the applicant.

Dated: June 26, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-17022 Filed 7-7-95; 10:53 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

National Biological Service

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). An expedited review has been requested in accordance with the Act so that approval can be received by August 18, 1995, permitting the National Biological Service to comply with Executive Order 12862 reporting requirements for 1995. Copies of the proposed collection of information and related forms may be obtained by contacting the Service's clearance officer at the phone number listed below. Comments and suggestions on the proposal should be made directly to the bureau clearance officer and the Office of Management and Budget, Paperwork Reduction Project, Washington, DC 20503, telephone (202) 395-7340.

Title: Generic Clearance for Measurement of Client Satisfaction with National Biological Service Products and Services

Abstract: The National Biological Service (NBS) is initiating a process with standard form to gather information about its customers' level of satisfaction with its products and services. When certain NBS products and services are delivered to a client, the client will also be given a Client Response sheet on which the client is invited to rate his/her satisfaction with the product or service and offer any additional comments he/she

wishes to make. The information from the responses will be summarized annually and the results used to improve NBS products and services. Copies of the final report of the summarized information will be provided to NBS' clients. This process and report will allow NBS to comply with Executive Order 12862 and the Government Performance and Results Act (44 U.S.C. Chapter 35)

Bureau Form Number: None

Frequency: Annually

Description of Respondents: Federal government officials and secondarily state and local government officials engaged in policy making, regulation, or management of public trust lands and resources

Estimated Completion time per

Respondent: 0.17 Hour

Individuals invited to Respond annually: 2000

Estimate annual Responses: 300

Annual Burden Hours: 50

Bureau Clearance Officer: Don Minnich, (202) 482-4838

Dated: June 23, 1995.

F. Eugene Hester,

Deputy Director.

[FR Doc. 95-16901 Filed 7-10-95; 8:45 am]

BILLING CODE 4310-DP-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32681]

H. Peter Claussen and Linda C. Claussen—Continuance in Control Exemption—Georgia & Florida Railroad Co., Inc.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission under 49 U.S.C. 10505 exempts from the prior approval requirements of 49 U.S.C. 11343, et seq., the continuance in control by H. Peter Claussen and Linda C. Claussen (the Claussens) of the Georgia & Florida Railroad Co., Inc. (G&F), upon G&F becoming a rail carrier, subject to standard labor protective conditions. The Claussens presently control Albany Bridge Company, Inc.; Gulf and Ohio Railways, Inc., which operates the Mississippi Delta Railroad and the Atlantic & Gulf Railroad; Wiregrass Central Railroad Company, Inc.; H&S Railroad Company, Inc.; Piedmont & Atlantic Railroad Co., Inc.; and Rocky Mount & Western Railroad Co., Inc. G&F filed a notice of exemption in Finance Docket No. 32680 to exempt its acquisition, lease, and

operation of certain rail lines and incidental trackage rights from the Norfolk Southern Railway Company and its subsidiaries, Georgia Southern and Florida Railway Company and Central of Georgia Railroad Company.

DATES: This exemption will be effective on August 10, 1995. Petitions to stay must be filed July 21, 1995. Petitions to reopen must be filed by July 31, 1995.

ADDRESSES: Send pleadings, referring to Finance Docket No. 32681 to: (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, 1201 Constitution Avenue, NW., Washington, DC 20423; and (2) Mark H. Sidman, 1350 New York Avenue, NW., Suite 800, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 927-5660. (TDD for the hearing impaired: (202) 927-5721).

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., Interstate Commerce Commission Building, 1201 Constitution Avenue, NW., Room 2229, Washington, DC 20423. Telephone: (202) 289-4357/4359. (Assistance for the hearing impaired is available through TDD services at (202) 927-5721).

Decided: June 23, 1995.

By the Commission, Chairman Morgan, Vice Chairman Owen, and Commissioners Simmons and McDonald.

Vernon A. Williams,

Secretary.

[FR Doc. 95-16946 Filed 7-10-95; 8:45 am]

BILLING CODE 7035-01-P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meeting

June 28, 1995.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended) notice is hereby given that a meeting of the National Council on the Humanities will be held in Washington, DC on July 20-21, 1995.

The purpose of the meeting is to advise the Chairman of the National Endowment for the Humanities with respect to policies, programs, and procedures for carrying out his functions, and to review applications for financial support and gifts offered to the Endowment and to make recommendations thereon to the Chairman.

The meeting will be held in the Old Post Office Building, 1100 Pennsylvania Avenue NW., Washington, DC. A portion of the morning and afternoon sessions on July 20-21, 1995, will not be open to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code because the Council will consider information that may disclose: Trade secrets and commercial or financial information obtained from a person and privileged or confidential; information of a personal nature the disclosure of which will constitute a clearly unwarranted invasion of personal privacy; and information the disclosure of which would significantly frustrate implementation of proposed agency action. I have made this determination under the authority granted me by the Chairman's Delegation of Authority dated July 19, 1993.

The agenda for the sessions on July 20, 1995, will be as follows:

8:30-9 a.m.—Coffee for Council Members—Room 527

Committee Meetings

(Open to the Public)—Policy Discussion 9-10 a.m.

Education Programs—Room M-14
Public Programs—Room 415
Research Programs—Room M-07
Preservation and Access & Challenge Grants—Room 315

Federal-State Partnership—Room 507
10 a.m. until Adjourned—(Closed to the Public)—Discussion of specific grant applications before the Council

The morning session on July 21, 1995, will convene at 10 a.m., in the 1st Floor Council Room, M-09, and will be open to the public, as set out below. The agenda for the morning session will be as follows:

(Coffee for Staff and Council members will be served from 9:30-10 a.m.)

Minutes of the Previous Meeting

Reports

- A. Introductory Remarks
- B. Introduction of New Staff
- C. Contracts Awarded in the Previous Quarter
- D. Budget Reports
- E. Legislative Report/Reauthorization
- F. Committee Reports on Policy and General Matters
- G. 1. Overview
2. Education Programs
3. Research Programs
4. Preservation and Access & Challenge Grants
5. Public Programs
6. Federal-State Partnership

(The meeting will be closed to the public at this point.)

The remainder of the proposed meeting will be given to the consideration of specific

applications (closed to the public for the reasons stated above).

Further information about this meeting can be obtained from Mr. David C. Fisher, Advisory Committee Management Officer, Washington, DC 20506, or call area code (202) 606-8322, TDD (202) 606-8282. Advance notice of any special needs or accommodations is appreciated.

David C. Fisher,

Advisory Committee Management Officer.

[FR Doc. 95-16853 Filed 7-10-95; 8:45 am]

BILLING CODE 7536-01-M

Meetings of Humanities Panel

AGENCY: National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, N.W., Washington, D.C. 20506.

FOR FURTHER INFORMATION CONTACT: David C. Fisher, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, D.C. 20506; telephone (202) 606-8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606-8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; or (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that these meetings will be closed to the public pursuant to subsections (c)(4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* July 31-August 1, 1995.

Time: 8:30 a.m. to 5 p.m.

Room: M-14.

Program: This meeting will review applications submitted to the Humanities